

SEP 17 2009

K091608

**BIOMET**  
MANUFACTURING CORP.

**510(k) Summary**

**Preparation Date:** May 29, 2009  
**Applicant/Sponsor:** Biomet Manufacturing Corp.  
**Contact Person:** Susan Alexander  
**Proprietary Name:** Cobalt™ MV Bone Cement  
**Common Name:** Bone Cement  
**Classification Name:** Polymethylmethacrylate (PMMA) Bone Cement (21 CFR §888.3027)  
**Product Code:** LOD

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**

Cobalt™ HV Bone Cement	K051496	Biomet Manufacturing Corp.
Simplex® P Radiopaque Bone Cement	N17004*	Stryker Howmedica Osteonics

**Device Description:** Cobalt™ MV Bone Cement is a methyl methacrylate-styrene copolymer based acrylic bone cement with a medium viscosity. Cobalt™ MV Bone Cement provides two separate, pre-measured sterilized components that when mixed form fast-setting radiopaque bone cement for use in orthopedic surgery.

**Intended Use:** Cobalt™ MV Bone Cement is an acrylic cement-like substance which allows seating and fixation of the prosthesis to the bone. After complete polymerization, the cement acts as a buffer for even weight distribution and other stresses between the prosthesis and the bone.

**Indications for Use:** Cobalt™ MV Bone Cement is indicated for use as bone cement in arthroplastic procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, nonunion of fractures of the neck and of the femur, sickle cell anemia osteoporosis, secondary severe joint destruction following trauma or other conditions (also for fixation of unstable fractures in metastatic malignancies), and revision of previous arthroplasty procedures.

**Summary of Technologies:** The technological characteristics of Cobalt™ MV Bone Cement are similar or identical to the predicate devices.

**Non-Clinical Testing:** Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

**Clinical Testing:** None provided as a basis for substantial equivalence.

*\*Approved prior to the downclassification of PMMA bone cements.*

All trademarks are property of Biomet, Inc., unless otherwise noted.  
Simplex® is a registered trademark of Stryker Howmedica Osteonics.

**Mailing Address:**  
P.O. Box 587  
Warsaw, IN 46581-0587  
Toll Free: 800.348.9500  
Office: 574.267.6639  
Main Fax: 574.267.8137  
www.biomet.com

**Shipping Address:**  
56 East Bell Drive  
Warsaw, IN 46582



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

SEP 17 2009

Biomet Manufacturing Corporation  
% Ms. Susan Alexander  
Regulatory Affairs Specialist  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K091608  
Trade/Device Name: Cobalt™ MV Bone Cement  
Regulation Number: 21 CFR 888.3027  
Regulation Name: Polymethylmethacrylate (PMMA) bone cement  
Regulatory Class: Class II  
Product Code: LOD  
Dated: September 1, 2009  
Received: September 2, 2009

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

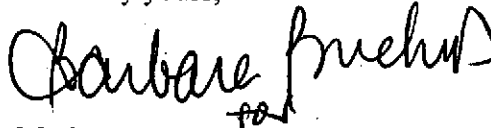
Page 2 - Ms. Susan Alexander

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Barbara Melkerson" with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Cobalt™ MV Bone Cement

### Indications For Use:

Cobalt™ MV Bone Cement is indicated for use as bone cement in arthroplastic procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, nonunion of fractures of the neck and of the femur, sickle cell anemia osteoporosis, secondary severe joint destruction following trauma or other conditions (also for fixation of unstable fractures in metastatic malignancies), and revision of previous arthroplasty procedures.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   NO    
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K091608